FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1851–1900

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *January 8, 1947.*

CONTENTS *

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1851. Misbranding of sulfathiazole tablets. U. S. v. The Lee Drug Co., Inc. Plea of nolo contendere. Fine, $750. (F. D. C. No. 16599. Sample Nos. 34413–F, 64235–F.)

INFORMATION FILED: January 2, 1946, Middle District of Georgia, against the Lee Drug Co., Inc., Columbus, Ga.

INTERSTATE SHIPMENT: On or about November 16, 1944, from Indianapolis, Ind.

LABEL, IN PART: "1000 No. 1635 Tablets Sulfathiazole (2- (p-aminobenzene-sulfonamido) thiazole) 0.5 Gm. (7.7 grs.) * * Caution—To be used only by or under the direct supervision of a physician."

NATURE OF CHARGE: That on or about December 13 and 14, 1944, the defendant removed a number of *sulfathiazole tablets* from the bottles labeled as above, repacked them into boxes bearing the label "Two every 4 hours," and sold them without a prescription.

The information charged further that the acts of the defendant resulted in the misbranding of the drug in the following respects: Section 502 (f) (1), the directions for use, "Two every 4 hours," borne on the boxes of the drug,

*For presence of a habit-forming narcotic without warning statement, see Nos. 1854, 1860; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 1854; omission of, or unsatisfactory, ingredients statements, Nos. 1854, 1889, 1891; failure to comply with the labeling requirements of an official compendium, No. 1869; cosmetics, subject to the drug provisions of the Act, Nos. 1884, 1885.

were not adequate directions for use; Section 502 (f) (2), the boxes containing the drugs bore no labeling containing warnings against use in those pathological conditions wherein use of the drug might be dangerous to health, or against unsafe dosage and methods and duration of administration; and, Section 502 (j), the drug, when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, "Two every 4 hours," was dangerous to health.

DISPOSITION: March 4, 1946. A plea of nolo contendere having been entered, the court imposed a fine of $750.

1852. Adulteration and misbranding of atropine sulfate ointment and Nepco Ammoniated Mercury Ointment, and misbranding of Nepco Ephedrine Nasal Jelly and Nepco Sulfur Ointment. U. S. v. New England Pharmaceutical Corporation. Plea of guilty. Fine, $50 on each of 5 counts; sentence suspended on count 6. (F. D. C. No. 17817. Sample Nos. 92835–F, 93003–F, 93701–F, 93703–F, 93707–F.)

INFORMATION FILED: April 12, 1946, Southern District of New York, against the New England Pharmaceutical Corporation, New York, N. Y.

ALLEGED SHIPMENT: On or about January 17 and October 23, 1944, from the State of New York into the District of Columbia and the State of New Jersey.

PRODUCT: Analyses disclosed that various tubes of the *atropine sulfate ointment* contained atropine sulfate in amounts varying from 0.46 percent to 2.60 percent; that the *nasal jelly* contained approximately 1 percent of ephedrine sulfate; that the *ammoniated mercury ointment* contained ammoniated mercury corresponding to 8.4 percent of mercury; and that the *sulfur ointment* was of U. S. P. strength.

NATURE OF CHARGE: *Atropine sulfate ointment.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that it was represented to contain 1 percent of atropine sulfate, whereas some of the tubes of the article contained less than 1 percent of atropine sulfate and other tubes contained more than 1 percent of atropine sulfate. Misbranding, Section 502 (a), the label statement, "Atropine Sulfate 1%," was false and misleading.

Ephedrine nasal jelly. Misbranding, Section 502 (a), the label statement, "For Head Colds, Etc., Subacute and Chronic Cases * * * used for relief of inflammatory condition of the Nose and Throat, such as Rhinitis, Laryngitis, Common Cold, Hay Fever, especially in subacute and chronic cases," were false and misleading since the article would not be an adequate treatment for head colds and other conditions suggested by the word "Etc."; it would not be an adequate treatment for subacute and chronic cases of head colds; and it would not be an adequate treatment for the relief of inflammatory conditions of the nose and throat, rhinitis, laryngitis, common colds, and hay fever, whether subacute and chronic or otherwise. Further misbranding, Section 502 (f) (2), the article contained ephedrine and its label failed to bear a warning that individuals suffering from high blood pressure, heart disease, diabetes, or thyroid trouble should not use the article except upon competent advice; and its labeling also failed to warn that frequent or continued use of the article might cause nervousness, restlessness, or sleeplessness.

Ammoniated mercury ointment. Adulteration, Section 501 (b), the article purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from the official standard in that it contained more than 4.5 percent of mercury, the maximum allowed by the standard, and its difference in strength from the standard was not plainly stated, or stated at all, on its label. Misbranding, Section 502 (a), the label statements, "Ammoniated Mercury Ointment U. S. P." and "Ammoniated Mercury U. S. P. XI," were false and misleading since the article did not consist of ammoniated mercury ointment that conformed to the requirements of the Pharmacopoeia. Further misbranding, Section 502 (a), the label statement, "A stimulant and parasiticide in cutaneous eruptions, as scabies, ringworm, exzema and porrigo," was false and misleading since it represented and suggested that the article would be an adequate treatment for cutaneous eruptions such as scabies, ringworm, eczema, and porrigo, whereas it would not be an adequate treatment for those conditions; Section 502 (f) (2), the labeling of the article failed to bear a warning that application of the article to large areas of the body might cause serious mercury poisoning; and, Section 502 (j), the article, because of its content of mercury, would be dangerous to health when used in